UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA AND THE STATES OF CALIFORNIA TEXAS, FLORIDA, OHIO, NORTH CAROLINA, OKLAHOMA, NEW YORK, HAWAII, MARYLAND, NEW JERSEY, *ex rel.* **[FILED UNDER SEAL]**

Plaintiffs,

v.

[FILED UNDER SEAL]

Defendants.

FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2) AND LOCAL CIVIL RULE 5.2(3)

DO NOT PLACE IN PRESS BOX
DO NOT ENTER ON PACER

CIVIL ACTION NO.

COMPLAINT

JURY TRIAL DEMANDED

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA AND THE STATES OF CALIFORNIA TEXAS, FLORIDA, OHIO, NORTH CAROLINA, OKLAHOMA, NEW YORK, HAWAII, MARYLAND, NEW JERSEY, *ex rel.* **ATUL JAIN**

Plaintiffs,

v.

DIOPSYS, INC., SEAN BAHRI, M.D, SEAN S. BAHRI, M.D., INC., DAVID MORA, DAVID SAUL MORA, O.D., PH.D., P.C., CLARK TSAI, M.D., CLARK S TSAI, M.D., INC., JAMES POWERS, M.D., HEALTHY VISION PROPERTY, LLC, ILONA GENIS, M.D., ILONA GENIS, MD, P.C., CHARLES ZWERLING, M.D., GOLDSBORO EYE CLINIC, PLLC, MICHAEL CHESTER, BRANDON CHESTER, CHESTER EYE CENTER, INC., GREGORY CLAY, TERRY FOSTER, RANDAL COX, FAMILY EYE CARE CLINIC, P.C., HAIDONG YANG, HAWAII RETINA, AHMED SAID, VATSAL DOSHI, M.D., VITREOUS RETINA MACULA SPECIALISTS OF NEW JERSEY, LLC, DAVID WARROW, M.D., ALLEN HU, M.D., JOHN WROBLESKI, M.D., CUMBERLAND VALLEY RETINA CONSULTANT, P.

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I. INTRODUCTION

1. Relator Atul Jain, M.D. ("Relator") brings this action on behalf of the United States and pursuant to California Insurance Code § 1871.7(b) to recover losses sustained by the Medicare Program, other federal payers, and private insurers as a result of the operations of Defendants Diopsys, Inc. ("Diopsys"), and 29 of its ophthalmologist and optometrist customers.

2. Electroretinography (ERG) is used by ophthalmologists and optometrists in rare occasions to measure the electrical response of the retina in response to a light stimulus. It can assist in the diagnosis of conditions related to the rods and cones of the retina. ERG encompasses several distinct procedures: full field electroretinography (ffERG) evaluates global retinal function, multifocal electroretinography (mfERG) provides a topographic measure of retinal function and localizes retinal activity within the central 30 degrees of vision (an area of the retina known as the macula), and pattern electroretinography (pERG) measures both macular and retinal ganglion cell electrical activity to help differentiate between diseases of macular versus optic nerve dysfunction. All ERG testing relies upon electrodes that measure the retina's response to light stimuli.

3. Visual Evoked Potential (VEP) is the recording of electroencephalographic activity generated at the visual cortex (located at the posterior portion of the occipital lobe of the brain) in response to visual stimulation. VEP testing is used to evaluate the integrity of the entire visual pathway: eye, optic nerve, optic tract, visual radiations, and the visual cortex. VEP testing can aid in diagnosing or identifying a defect in the integrity of the visual pathway, but cannot provide details specific to retinal function. To perform a VEP test, reference and active electrodes are placed on the patient's scalp, near the forehead and the back of the head. The patient then typically covers one eye at a time and observes stimuli on a screen several feet away. In contrast with ERG testing, retinal electrodes are not used, and localized retinal activity cannot be observed, isolated, or quantified using VEP testing.

4. Until 2019, Medicare reimbursed providers approximately $109 for medically necessary ERG tests. Claims to Medicare for ERG tests have exploded over the past decade. In

2012, there were only 5,246 claims to Medicare, nationwide. Just three years later, in 2015, providers submitted 97,018 claims for ERG tests to Medicare, at a $10.5 million cost to the taxpayer. By 2018, claims reached 126,191, resulting in reimbursements of $14 million from Medicare. Beginning January 1, 2019, ERG testing was broken up into three separate CPT codes: 92273 for ffERG; 92274 for mfERG; and 0509T for PERG. Medicare reimburses providers approximately $134, $91, and $79, respectively, for these tests when medically necessary. Thus, on a single day, for one eye of one patient, ERG testing can lead to reimbursement of $304.

5. Medicare reimburses providers approximately $96 for medically necessary VEP tests. Claims to Medicare for VEP steadily rose from 23,358 in 2012 until they peaked at 81,763 in 2015. Since, VEP claims have slowly decreased to 56,947 in 2018. However, 2018 Medicare reimbursements totaled just over $3 million.

6. This dramatic increase in ordering of ERG and VEP tests can be traced back largely to the fraud of one company—Diopsys Inc.—and several of its medical provider customers. Diopsys manufactures what it refers to as a "vision testing system" that comes in three versions: (1) a cart-based system, "NOVA"; (2) a tabletop system, "ARGOS"; and (2) a portable system, the "RETINA PLUS." All three of these systems, it claims, can perform ERG and VEP procedures that are reimbursable by Medicare and other payers.

7. Diopsys' systems, however, are based on bad science. They cannot, in fact, perform legitimate ERG tests. Diopsys markets its machines as being able to perform, in one minute, tests that would normally take at least 30 minutes, can be run on several patients each day, can be repeated at each visit, and can be billed out at over $300 per eye, per day. Diopsys encourages providers to maximize reimbursements by billing for all three ERG CPT codes (or all three ERG codes and VEP testing), specifically highlighting that CPT codes "are not bundled or exclusionary." In order to double reimbursement and avoid detection of overutilization, Diopsys even recommends that each eye be tested on separate days.

8. Worse still, Diopsys knowingly encourages physicians to use its machines for conditions and diseases for which ERG and VEP are not a medically necessary diagnostic tool.

Put differently, even if its machines could perform legitimate ERG and VEP tests, Diopsys is knowingly causing physicians to order the tests on thousands of patients for which there is no benefit—all at a cost of millions of dollars to the Medicare program.

9. Finally, and most blatantly illegal, Diopsys' ERG machines have never been approved by the FDA, and are therefore ineligible for reimbursement by Medicare, Medicaid, and most other payors. Diopsys received FDA 510(k) approval for its NOVA system in 2011, when the system only included VEP testing equipment. Two years later, it added ERG equipment to the system. Though the system kept the same name—NOVA—as the device approved in 2011, it was materially and significantly changed when Diopsys added the ERG function to it. Under strict FDA rules, Diopsys was required to seek approval for the new device, but never did. Accordingly, for the past 8 years, Diopsys has been successfully marketing an adulterated medical device to physicians around the country, leading to tens of millions of dollars in claims and reimbursements from Medicare and other payors.

10. Relator brings this case under the False Claims Act and its state-law corollaries to put an end to Defendants' fraud and recover the millions in taxpayer money that has been wasted on medically unnecessary testing performed on adulterated and unapproved medical devices.

II. JURISDICTION AND VENUE

11. This Court has jurisdiction over the False Claims Act ("FCA") causes of action raised in this complaint under 28 U.S.C. § 1331, as they arise under Federal law. This Court also has jurisdiction over the FCA claims pursuant to 31 U.S.C. § 3732, which confers jurisdiction for claims brought under the FCA on the District Courts of the United States.

12. Additionally, this Court has supplemental jurisdiction over the state law claims in this action pursuant to 31 U.S.C. § 3730(b), as they arise from the same transactions and occurrences as the FCA claims.

13. Venue is proper pursuant to 31 U.S.C. § 3732(a), as Diopsys transacts business in this district, and orchestrated its violations of the FCA in this District.

III. PARTIES

14. The Plaintiffs in this action are the United States of America ("United States"), the State of California, the State of Texas, the State of Florida, the State of New York, the State of North Carolina, the State of Hawaii, the State of New Jersey, the State of Oklahoma , and the State of Maryland by and through Relator Atul Jain, M.D.

15. Defendant **Diopsys, Inc.**, is a Delaware corporation with its principal place of business at 16 Chapin Rd., Suite 912, Pine Brook, N.J., 07058.

16. Defendant **Sean Bahri, M.D.**, practices in Newport Beach, CA via his medical corporation, Defendant **Sean S. Bahri, M.D., Inc.** His National Provider Number (NPI) is 1821273137.

17. Defendant **David Mora** (Optometrist), practices in Laredo, Texas, via his medical corporation, Defendant **David Saul Mora, O.D., Ph.D., P.C.**, and doing business as the Mora Eye Clinic. His National Provider Number (NPI) is 1255305256.

18. Defendant **Clark Tsai, M.D.** practices in Concord, California, via his medical corporation, **Clark S. Tsai, M.D., Inc.** His National Provider Number (NPI) is 1720096829.

19. Defendant **James Powers, M.D.** practices in Saint Petersburg and New Port Richey, Florida, through his medical corporation, Defendant **Health Vision Property, LLC**, and doing business as Healthy Vision Institute. Dr. Powers previously operated through Health Vision Optical, Inc., which is currently inactive. His National Provider Number (NPI) is 1578553574.

20. Defendant **Ilona Genis, M.D.** practices in Brooklyn, New York, through her medical corporation, Defendant **Ilona Genis MD, P.C.** Her National Provider Number (NPI) is 1063415537.

21. Defendant **Charles Zwerling, M.D.** practices in Goldsboro, North Carolina, through his medical clinic, Defendant **Goldsboro Eye Clinic, PLLC**. His National Provider Number (NPI) is 1750313599.

22. Defendants **Michael Chester** (Optometrist) and **Brandon Chester** (Optometrist) practice in Chillicothe, Ohio, as owners of Defendant **Chester Eye Center, Inc.** Michael's

National Provider Number (NPI) is 1780686774; Brandon's is 1386844348. Michael previously operated via his medical corporation, Michael E. Chester, O.D., Inc.

23. Defendant **Gregory Clay** practices in Durant, Oklahoma. His National Provider Number (NPI) is 1023031994.

24. Defendants **Terry Foster** (Optometrist) and **Randal Cox** (Optometrist) practice together at Defendant **Family Eye Care Clinic, P.C.** in Atlanta, Texas. Foster's National Provider Number (NPI) is 1740251867; Cox's NPI is 1831160951.

25. Defendant **Haidong Yang** (Optometrist) practiced at Defendant **Hawaii Retina** in Hilo, Hawaii. His National Provider Number (NPI) is 1245204437.

26. Defendant **Ahmed Said** (Optometrist) practices in Dunn, North Carolina, as Oasis Eye Care. His National Provider Number (NPI) is 1245251529.

27. Defendant **Vatsal Doshi, M.D.** practices in Milburn, New Jersey, through his medical corporation, Defendant **Vitreous Retina Macula Specialists of New Jersey, LLC**. His National Provider Number (NPI) is 1831394899.

28. Defendants **David Warrow, M.D., Allen Hu, M.D.,** and **John Wroblewski, M.D.**, practice together at Defendant **Cumberland Valley Retina Consultants**, which has offices in Hagerstown, MD, Chambersburg, PA, and Martinsburg, WV. Dr. Warrow's National Provider Number (NPI) is 1275776049; Dr. Hu's NPI is 1235315268; and Dr. Wroblewski's is 1477521334.

IV. OVERVIEW OF THE SCHEME

A. The United States Medicare System

29. Medicare is a federally funded health care program that provides medical insurance coverage to qualified residents of the United States who are aged 65 and older, younger people with permanent or congenital disabilities, or those who meet other special criteria like the End Stage Renal Disease program. The vast majority of Medicare's costs are paid by United States citizens through their taxes. Medicare pays for medical expenses, such as doctor visits, diagnostic testing and imaging, and hospital stays.

30. Title XVII of the Social Security Act establishes the Medicare Program (technically, the "Health Insurance for the Aged and Disabled Program"). See 42 U.S.C. § 1397 *et seq*.

31. The United States provides reimbursement for Medicare claims from the Medicare Trust Funds through the Centers for Medicare & Medicaid Services ("CMS"), which is the operating division of the United States Department of Health & Human Services ("HHS"). CMS, in turn, contracts out to Medicare Administrative Contractors ("MACs"), also known as carriers, to review, approve, and pay Medicare claims received from healthcare providers.

32. Medicare payments are typically made directly to healthcare providers rather than the patient, as Medicare recipients routinely assign their right to payment to the healthcare provider. Once a Medicare recipient assigns their rights to payment to a provider, the provider then submits its bill directly to Medicare for payment.

33. To bill Medicare, a provider must submit an electronic or hard-copy claim form called a CMS-1500 form. When submitting the form, the provider must certify that the services in question were "medically indicated and necessary for the health of the patient."

34. The CMS-1500 form requires the provider to state, among other things, the procedure(s) for which it is billing Medicare, the provider number, the identity of the patient, and a short narrative explaining the diagnosis and the medical necessity of services that the provider rendered.

35. All healthcare providers must comply with all applicable statutes, regulations, and guidelines in order to be reimbursed by Medicare. Providers have a duty to have knowledge of the relevant statutes, regulations, and guidelines regarding coverage for Medicare services.

36. For example, Medicare reimburses only reasonable and necessary medical services furnished to beneficiaries. *See* 42 U.S.C. § 1395y(a)(1)(A); *see also* 42 C.F.R. § 411.115(k). Providers must also assure that they provide medical services to Medicare recipients "economically and only when, and to the extent, medically necessary." 42 U.S.C. § 1320c-5(a)(1).

37. Because it is not realistically feasible to review medical documentation before paying each claim, MACs generally make payment under Medicare based on the providers' certification on the Medicare claim form that the services in question were "medically indicated and necessary for the health of the patient."

B. ERG Testing and its Limited Uses

38. An ERG test uses electrodes to measure the retina's response to light stimuli and assess retinal function. Initially, Burian-Allen (BA) electrodes, which are placed directly on the cornea via contact lens, were exclusively used for ERG testing. Dawson-Trick-Litzkow (DTL) electrodes, which do not require a contact lens and instead rest on the cornea via conjunctival wire, became more popular given their increased comfort and comparable signal strength to BA electrodes (which are considered the "gold standard"), as confirmed by several peer reviewed medical publications. Skin electrodes are placed on the skin of the patient's eyelid and provide a substantially weaker signal.[1] As such, they have traditionally been reserved for pediatric patients who have a lower tolerance for discomfort. When BA or DTL electrodes are used, the retina's response can be measured against a stable, "distant reference electrode." This process cannot be mimicked with skin electrodes.

39. ERG has extremely limited uses. It is primarily utilized for investigating unexplained loss of vision and hereditary retinal dystrophies. Most ethical optometrists and ophthalmologists only order an ERG test a handful of times per year.

40. ERG manufacturers have attempted to broaden its uses over the past decades, but those efforts have largely failed, and its legitimate uses remain limited. Most notably, ERG is almost universally considered not to be a reliable method for diagnosing or managing glaucoma. Accordingly, the vast majority of payers, including Medicare in much of the country, do not pay for ERG use in connection with glaucoma.

[1] Esakowitz L, Kriss A, Shawkat F. A comparison of flash electroretinograms recorded from Burian Allen, JET, C-glide, gold foil, DTL and skin electrodes.

41. For example, LCD L37398 issued by First Coast Service Options, Inc., covering jurisdictions J – N (Florida, Puerto Rico, Virgin Islands), and LCD L37373, issued by Novitas Solutions, Inc., covering Jurisdictions J – H (Colorado, New Mexico, Oklahoma, Texas, Arkansas, Louisiana, Mississippi, Delaware, District of Columbia, Maryland, New Jersey, and Pennsylvania), both state:

> "The use of ERG for glaucoma (either diagnosis or management) is considered experimental and investigational as the available published clinical evidence does not support clinical value. Therefore, the use of ERG (all forms: ERG, mfERG, PERG, etc.) for glaucoma is non-covered and will be denied as not reasonable and necessary."

42. Similarly, LCDs issued by Wisconsin Physicians Service Insurance Corporation (L37015), covering Medicare jurisdiction J – 05 (Iowa, Kansas, Missouri, Nebraska, Indiana, and Michigan), and National Government Services, Inc. (LCD L36831), covering Medicare jurisdictions J and K (Illinois, Minnesota, Wisconsin, Connecticut, New York, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont), state that both administrators "consider[] the use of VEP or ERG for either glaucoma diagnosis or management investigational" and non-covered.

43. Although the other Medicare MACs have not issued LCDs specific to ERG, all reliable industry sources confirm that the legitimate uses of ERG are relatively limited, and do not include detection and treatment of glaucoma.

44. For example, the leading professional group in eye medicine, the American Academy of Ophthalmology (AAO), publishes "preferred practice patterns" (PPP) that detail standard practices for diagnosing and treating common eye conditions. None of the PPP mention, let alone recommend, any type of ERG for the diagnosis or management of glaucoma or other common eye conditions.

45. The only PPP that mention ERG relate to drug toxicities and inherited retinal disorders; both extremely rare situations. Accordingly, even in those jurisdictions without a

published LCD specific to ERG, routine use of ERG for glaucoma (and most other eye conditions) is not reasonable or necessary.

C. VEP Testing and its Limited Uses

46. To perform a VEP test, electrodes are placed on the forehead, the skin near the temple, and the back of the head. Much like a traditional vision test, the patient covers one eye and looks at an image on a screen several feet away. The electrical signal that is sent to the patient's visual cortex (located on the posterior aspect of the brain) is recorded. VEP tests measure activity in the visual pathway and have limited localizing ability. Put simply, VEP tests can identify whether a visual signal is making its way to the brain but cannot identify the cause or location of any problem.

47. As with ERG, the use of VEP for diagnosing or managing glaucoma is considered investigational and not covered by several Medicare carriers. WPS GHA and AOO's 2011 reports both reached the conclusion that VEP does not produce "definitive guidance on the diagnosis of glaucoma or its progression over time." Like ERG testing, the 2015 PPP guidelines do not recommend nor mention VEP as a diagnostic or treatment tool for glaucoma, and at least two Medicare Administrators explicitly state that it is non-covered (see ¶ 41 above).

D. Diopsys Markets its Tests for Diagnosis and Treatment of Glaucoma and Other Conditions with Full Knowledge that such Tests are not Reimbursable

48. Despite the explicit use and coverage limitations of ERG and VEP, Diopsys has aggressively marketed its machines to physicians and other providers as valid diagnostic and treatment tools for glaucoma and other fairly common conditions including CRVO (central retinal vein occlusion), macular degeneration, diabetic retinopathy, and diabetic macular edema. Furthermore, Diopsys encourages providers to bill Medicare and other payers for using its machines in these non-covered ways. Diopsys even provides multiple billing "cheat sheets" to its customers that summarize the conditions it recommends ordering the ERGs in connection with, along with the expected reimbursement amounts. In one such cheat sheet, it recommends CPT

codes 92273 or 0509T for "Glaucoma signs or symptoms," and lists an expected reimbursement of $147.07 for code 92273, and $86.70 for code 0509T.

49. Another cheat sheet that Diopsys provides customers is an Excel workbook entitled "Clinical Utilization Worksheet for Visual Electrophysiology." The spreadsheet instructs providers to: "Use this worksheet to review your patient's needs for Electroretinography and Visual Evoked Potential, for diagnosis and/or earlier treatment decisions, to measure disease progression or improvement to visual function after treatment." The spreadsheet then lists a variety of "Clinical Indications" for which Diopsys recommends testing, provides diagnosis codes to utilize in connection with billing, and calculates the expected reimbursement to the provider. Several of the "Clinical Indications" are glaucoma-related, but under a different name. For example, "RNFL abnormality," "glaucomatous or disc abnormal," and "RNFL defect" are all synonymous with glaucoma—for which these tests should not be billed to Medicare or most other payers. In fact, a much more accurate test for detecting actual structural changes in the RNFL exists, as described by CPT 92133 (Scanning computerized ophthalmic diagnostic imaging, posterior segment, with interpretation and report, unilateral or bilateral; optic nerve). CPT 92133 reimburses approximately $37.68, and is the preferred testing method for glaucoma among both glaucoma and retina specialists.

50. In its marketing pitch to potential physician customers, Diopsys focuses on the money-making proposition of its machines. For example, in one such pitch, when justifying the cost of the machine, a Diopsys representative provided the following guidance, including running the test on every patient with suspected glaucoma at least once per year, per eye, and as frequently as quarterly:

Protocol suggest that practitioners run VEP ($75.05) annually and ffERG ($147.07) twice annually, often on the same patient. $75.05 + $147.07 = $222.12)
Toxicity (Plaquenil) patients; practitioner should obtain a base-line and re-run annually or twice annually, depending on results. ($99.01)
Glaucoma suspects should be scanned annually and re-ran every 6-months or every 3-months depending on results. VEP annually is often scanned on the same visit. ($222.12)
Any patients receiving Anti-VEGF injections for DR, CRVO, Uveitis (ffERG $147.07); protocol suggest ffERG following every two injections.
AMD (both wet & dry) – once to twice annually.

Two patients per day between the 4 doctors (10 patients per week); $222 x 20 days per month = around $8880 per month minus $800 (sensor cost) over 6 months = $48,000
If your office utilizes this technology on 4 patients per day, return on investment will happen within 3 months.

In another e-mail, the Diopsys representative pitched the system's "ffERG" as a "one-minute test" that gives "doctors the ability to address diabetic issues earlier and the ability to detect glaucoma years before the on-set." He further emphasized that the ffERG is "billable under CPT-99273 at $147.00."

51. In a pitch to another practice, after conducting an in-office demonstration, the Diopsys representative highlighted that with just the seven demo patients, "that represents more than $1000 in incremental revenue, not to mention the beneficial diagnostic information to help you better manage your patient's treatments. The longer you delay, the larger the dollar amount of missed profits."

E. Diopsys' Marketing Efforts were Highly Successful; It Has Caused Extreme Overutilization and the Submission of False Claims for Medically Unnecessary Testing.

52. Diopsys' aggressive marketing efforts have succeeded, and caused a massive increase in utilization of ERG and VEP for non-covered uses.

53. Diopsys introduced its ERG testing machine in 2013. Consequently, between 2012 and 2018, the number of claims to Medicare for ERG testing increased *25-fold*. Similarly, after Diopsys introduced VEP testing for adults in 2011, the claims to Medicare for VEP testing more than tripled from 2012 to 2015. Much of this increase is due to Diopsys' aggressive and inappropriate marketing techniques, as well as doctors who eagerly adopted Diopsys' profit-driven approach to ophthalmic testing.

54. In 2018, Medicare reimbursed a total of $14,093,278 for 126,191 ERG tests under CPT code 92275, performed by 2,792 eye doctors. Consistent with the relatively rare need for ERG testing, the vast majority of these providers ordered 10 or fewer over the course of the *entire year*. A small handful of providers, however, drove massive ordering, and Medicare reimbursement. For example, the top 100 ordering providers, nationwide, were responsible for ordering 48,204 of these procedures—38% of the entire Medicare total. The top 10 ordering

providers in the country were responsible for 10,232 tests, resulting in 8.1% of the entire Medicare expenditures for the year on CPT code 92275.

55. Of these outlier physicians, many, if not most, were driven to order and perform high numbers of CPT code 92275 after buying in to Diopsys' fraudulent marketing scheme.

56. By way of comparison, some of top inherited retinal disease and dystrophy specialists—who are most likely to see patients in need of ERG testing—ordered relatively few ERG tests in 2018:

- Dr. Michael Gorin (UCLA): 63
- Dr. Mark Pennesi (OHSU): 19
- Dr. Paul Yang (OHSU): 52
- Dr. Loh-Shan Leung (Stanford): 27
- Dr. Mandeep Singh (Johns Hopkins): 145
- Dr. Henry Ferreyra (UCSD): 14
- Dr. Kanishka Jayasundera (Kellogg Eye Center, University of MI): 45
- Dr. Abigail Fahim (Kellogg Eye Center, University of MI): 48
- Dr. Nieraj Jain (Emory): 47

57. In 2018, Medicare reimbursed a total of $3,253,182 for 62,290 VEP tests under CPT code 95930, performed by 2,553 eye doctors. The vast majority of these providers ordered fewer than 10 VEP tests on Medicare beneficiaries for the entire year. However, like with ERG, a small number of providers accounted for a significant percentage of the ordering and Medicare reimbursement. The top 50 providers ordered 22,578 VEP tests—36.2% of all tests ordered in 2018, accounting for 37.9% of Medicare reimbursements. The top 10 providers ordered 9,253 VEP tests—14.9% of all VEP tests submitted to Medicare for reimbursement in 2018.

58. Most of these outlier providers were driven to that status through use of Diopsys' machines.

59. For example, the most prolific user of CPT code 92275 in 2018, **Sean Bahri, M.D.**, uses Diopsys machines on patients with suspected or confirmed glaucoma. In 2018, he submitted

1,836 claims to Medicare for CPT code 92275 and was reimbursed $249,696. Dr. Bahri also ranked 30th in VEP tests in 2018, submitting 333 claims to Medicare for CPT code 95930 for a total reimbursement of $21,312. Dr. Bahri practices in Newport Beach, CA. His National Provider Number (NPI) is 1821273137.

60. The second-most prolific user of CPT code 92275 from 2012 to 2018, **David Mora, OD** (an optometrist), uses Diopsys machines on patients with suspected or confirmed glaucoma. In 2018, he submitted 832 claims to Medicare for CPT code 92275 and was reimbursed $89,325. He is also a prolific utilizer of VEP testing (CPT code 95930). In 2018 alone, he submitted 646 claims to Medicare and was reimbursed an average of $50 per claim. Dr. Mora practices in Laredo, Texas. His National Provider Number (NPI) is 1255305256.

61. The second-most prolific user of CPT code 92275 in 2018, **Clark Tsai**, **M.D.**, uses Diopsys machines on patients with suspected or confirmed glaucoma. In 2018, he submitted 1,143 claims to Medicare for CPT code 92275 and was reimbursed $170,346. Dr. Tsai also ranked second in VEP tests in 2018, submitting 1,141 claims to Medicare, and receiving an average of $71 per claim. Dr. Tsai practices in Concord, California. His National Provider Number (NPI) is 1720096829.

62. The third-most prolific user of CPT code 92275 in 2018, **James Powers, M.D.**, uses Diopsys machines on patients with suspected or confirmed glaucoma. In 2018, he submitted 1,049 claims to Medicare for CPT code 92275 and was reimbursed $116,236. Dr. Powers also ranked sixth in VEP tests in 2018, submitting 785 claims to Medicare for CPT code 95930 for a total reimbursement of $40,864. Dr. Powers practices at the Healthy Vision Institute in St. Petersburg and New Port Richey, Florida. His National Provider Number (NPI) is 1578553574.

63. The fourth-highest utilizer of CPT code 92275 in 2018, **Ilona Genis, M.D.**, uses Diopsys on patients with suspected or confirmed glaucoma. In 2018, she submitted 975 claims to Medicare for CPT code 92275 and was reimbursed $131,236. Dr. Genis also submitted 95 claims to Medicare for CPT code 9530 and was reimbursed $6,270. Dr. Genis practices in Brooklyn, New York. Her National Provider Number (NPI) is 1063415537.

64. The fifth-highest utilizer of CPT code 92275 in 2018, **Charles Zwerling, M.D.**, uses Diopsys on patients with suspected or confirmed glaucoma. In 2018, he submitted 940 claims to Medicare for CPT code 92275 and was reimbursed $105,637. Dr. Zwerling also ranked third in VEP testing in 2018, submitting 1,044 claims to Medicare for CPT code 95930 for a total reimbursement of $54,277. Dr. Zwerling practices at the Goldsboro Eye Clinic in Goldsboro, North Carolina. His National Provider Number (NPI) is 1750313599.

65. The sixteenth-highest utilizer of CPT code 92275 in 2018, **Michael Chester** (Optometrist), uses Diopsys on patients with suspected or confirmed glaucoma. In 2018, he submitted 709 claims to Medicare for CPT code 92275 and was reimbursed $77,815. His partner, **Brandon Chester**, submitted an additional 521 claims to Medicare for CPT code 92275, and was reimbursed $56,942. Michael Chester also ranked in the top 50 for VEP testing in 2018, submitting 221 claims to Medicare for CPT code 95930 for a total reimbursement of $10,796; Brandon submitted an additional 213, and was reimbursed $10,647. The Chesters practice in Chillicothe, Ohio. Michael's National Provider Number (NPI) is 1780686774; Brandon's is 1386844348.

66. **Gregory Clay** (Optometrist) uses Diopsys on patients with suspected or confirmed glaucoma. In 2018, he submitted 558 claims to Medicare for CPT code 92275 and was reimbursed $58,935. Clay also submitted 136 claims to Medicare for CPT code 95930 for a total reimbursement of $6,861. Chester practices in Durant, Oklahoma. His National Provider Number (NPI) is 1023031994.

67. **Terry Foster** and **Randal Cox** (Optometrists) practice together at the Family Eye Care Clinic in Atlanta, Texas. Foster and Cox use Diopsys on patients with suspected or confirmed glaucoma. In 2018, together they submitted 762 claims to Medicare for CPT code 92275 and were reimbursed $80,156. They also submitted 559 claims to Medicare in 2018 for CPT code 95930 for a total reimbursement of $28,724. Foster's National Provider Number (NPI) is 1740251867; Cox's NPI is 1831160951.

68. **Haidong Yang** (Optometrist) uses Diopsys on patients with suspected or confirmed glaucoma. In 2018, he submitted 482 claims to Medicare for CPT code 92275 and was reimbursed $62,225. Yang practices in Hilo, Hawaii. His National Provider Number (NPI) is 1245204437.

69. The ninth-highest utilizer of VEP testing in 2018, **Ahmed Said** (Optometrist), uses Diopsys on patients with suspected or confirmed glaucoma. In 2018, he submitted 633 claims to Medicare for CPT code 95930, and was reimbursed an average of $49 per claim. He is also a prolific utilizer of ERG codes, submitting 638 claims to Medicare for CPT code 92275 in 2018, and receiving reimbursement of $67,693. Dr. Said practices in Dunn, North Carolina. His National Provider Number (NPI) is 1245251529.

70. The twelfth-highest user of CPT code 92275 in 2018, **Vatsal Doshi, M.D.**, uses Diopsys on patients with suspected or confirmed glaucoma. In 2018, he submitted 789 claims to Medicare for CPT code 92275 and was reimbursed $105,951. Dr. Doshi practices in Milburn, New Jersey. His National Provider Number (NPI) is 1831394899.

71. **David Warrow, M.D., Allen Hu, M.D.,** and **John Wroblewski, M.D.**, practice together at **Defendant Cumberland Valley Retina Consultants**, which has offices in Hagerstown, MD, Chambersburg, PA, and Martinsburg, WV. In 2018, Dr. Warrow submitted 203 claims to Medicare for CPT code 92275 and was $25,284. In 2018, Dr. Hu he submitted 15 claims to Medicare for CPT code 92275 and was reimbursed $1,899. In 2018, Dr. Wroblewski submitted 54 claims to Medicare for CPT code 92275 and was reimbursed $6,701. Dr. Wroblewski serves as a paid consultant for Diopsys and promotes its use through speaking engagements and webinars.

72. The foregoing claims (and similar claims in other years) were false, as they were not medically necessary. Based on direction and guidance from Diopsys, the Defendant Doctors performed unnecessary ERG and VEP tests. Additionally, as described in the following sections, Diopsys' testing equipment is adulterated, and ineligible for reimbursement by Medicare.

F. The Diopsys Machines Are not FDA Approved, and Do Not Provide Accurate and Useful Information

73. Worse still, Diopsys' machines do not perform legitimate ERG testing, and have not been approved by the FDA.

74. As described above, ERG tests involve electrodes placed directly on the eyeball or eyelid. VEP tests involve electrodes placed on the scalp. In laypersons terms, ERG tests detect problems within the eye; VEP tests detect problems between the eye and the brain. Though often marketed and utilized together, ERG and VEP are distinct tests, using distinct mechanisms and equipment for very different diagnoses and conditions.

75. In 2005, Diopsys received FDA Section 510(k) clearance to market a VEP vision testing device, the "Enfant." The Enfant's intended use was for "visual disorders in infants and pre-school children."[2]

76. In 2011, Diopsys received 510(k) clearance for a second VEP device, the "NOVA."[3] Diopsys asserted substantial equivalence to its own product, the Enfant, and VeriSci's Neucodia, a VEP testing device for adults. The NOVA was presented to the FDA as "an electrophysiological device that generates photic stimuli, and records, processes and analyzes the resultant visual evoked potential (VEP) signals to provide information about the visual system [sic] structural and neural abnormalities."[4] The NOVA's target population was infants, preschool children, children, and adults. There was no mention of ERG testing in Diopsys' submission to the FDA for approval of the NOVA device. In accordance with the application, the FDA approved NOVA for VEP testing. The approved indications for use are limited to VEP testing, and nowhere mention ERG testing.

77. Two years after receiving FDA 510(k) approval of the NOVA device, Diopsys modified the NOVA device to include ERG testing equipment. Diopsys never applied for, or received, FDA approval for the modified device, in contravention of FDA regulations.

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[2] https://www.accessdata.fda.gov/cdrh_docs/pdf4/K043491.pdf
[3] https://www.accessdata.fda.gov/cdrh_docs/pdf10/K101763.pdf
[4] *Id.*

78. 21 CFR 807.81(a)(3) instructs that premarket notification must be submitted when:

> (3) The device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture, or intended use. The following constitute significant changes or modifications that require a premarket notification:
>
> > (i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process.
> >
> > (ii) A major change or modification in the intended use of the device.

79. Failure to make required pre-market notifications resulting from significant change or modification renders the device "adulterated and misbranded" and ineligible for Medicaid and Medicare reimbursement.[5]

80. When it added ERG testing equipment to its NOVA device, Diopsys significantly changed and modified its device in terms of its design and intended use. Nonetheless, it has never sought FDA approval of the modified device. Accordingly, every claim for ERG testing on a Diopsys machine was performed on adulterated and misbranded equipment and was ineligible for reimbursement.

[5] United States ex rel. Wood v. Avalign Techs., Inc., 2020 WL 2555115 at 2* (S.D.N.Y. May 20, 2020) (citing 21 U.S.C. §§ 331(p), 351(f), 352(o).

81. To perform Diopsys' VEP test, electrodes are placed on the forehead above the eyebrows, the skin near the temple, and the back of the head. Much like a traditional vision test, the patient covers one eye and looks at an image on a screen several feet away, without dilation of the pupil. The electrical signal that is sent to the patient's visual cortex is recorded. VEP tests measure activity in the visual pathway but have little to no localizing ability.

Diopsys VEP test

82. According to Diopsys, their VEP testing can help diagnose and manage neuro-visual disorders such as optic neuritis, amblyopia, and vision problems due to TBI.[6]

83. The focus of ERG testing, on the other hand, is retinal activity. To perform an ERG test, electrodes must be placed directly on or near the cornea (clear part of the eyeball). Diopsys uses sensory pads containing electrodes that are placed on the patient's eyelids. Rather

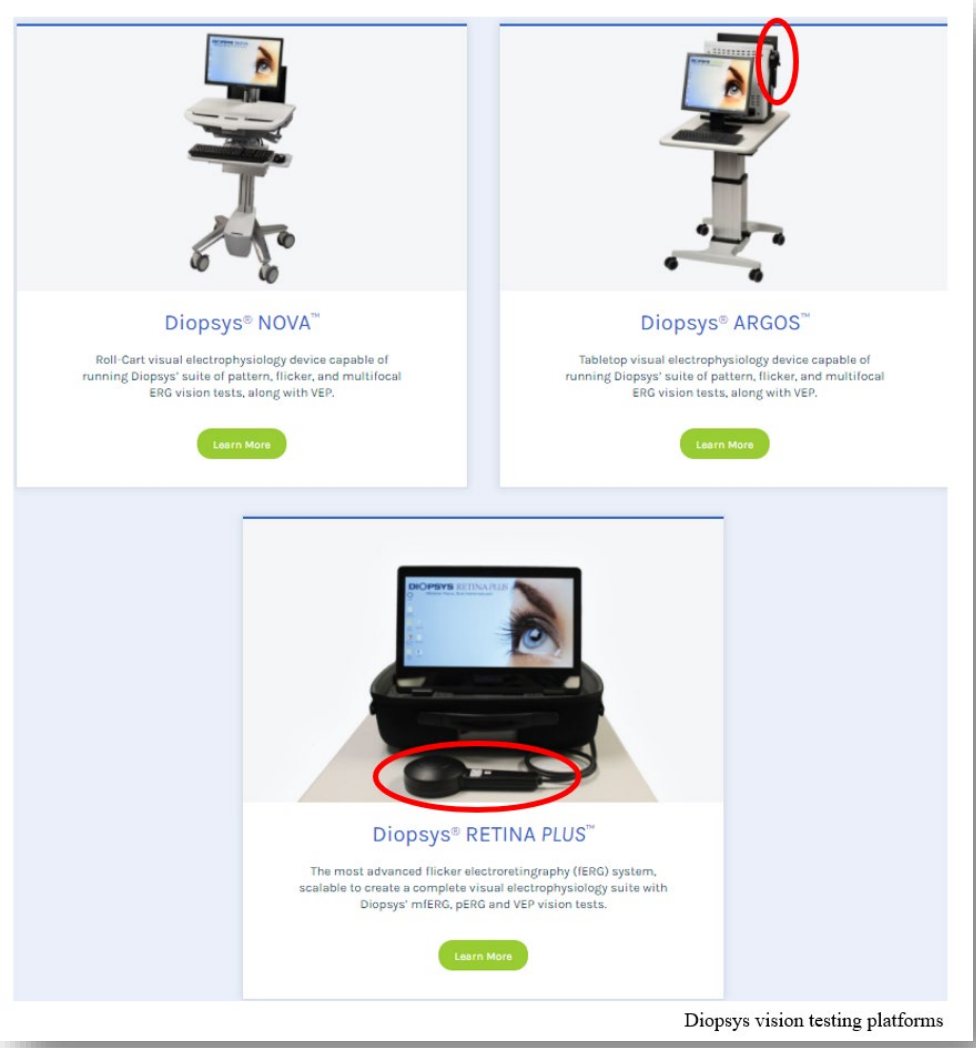
Diopsys ERG test

than using a screen, a handheld device pressed against the cheek and eyebrow introduces a series

[6] https://diopsys.com/visual-electrophysiology-products/visual-evoked-potential-vep/

of flashing lights to the patient's eye. The retina's response is then recorded. Diopsys devices perform three distinct ERG tests, ffERG, mfERG, and PERG. Diopsys advertises that its ERG testing helps physicians diagnose and manage retinal disorders, diseases including glaucoma, drug-induced retinopathy, and retinal toxicity.[7]

84. Diopsys markets three vision testing systems that can purportedly perform VEP and ERG testing: the NOVA, ARGOS, and RETINA PLUS. The ARGOS and RETINA PLUS are the tabletop and carry case versions of the NOVA, respectively. They are pictured on the Diopsys website as including the handheld device that is essential for ERG testing.

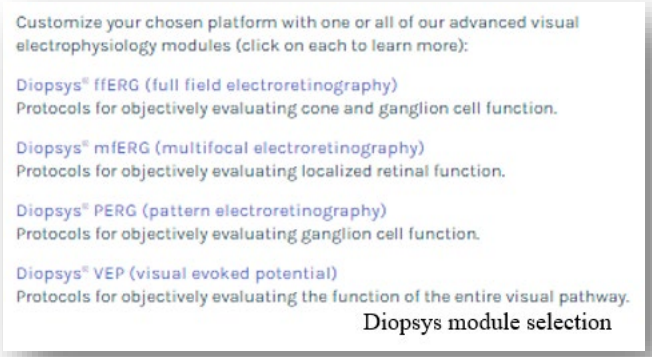


Diopsys vision testing platforms

[7] https://diopsys.com/visual-electrophysiology-products/full-field-electroretinography/

However, neither the NOVA, ARGOS, or RETINA PLUS ever received FDA approval for ERG testing, or for the handheld device used for ERG testing, which Diopsys added in or about 2012.

85. In fact, Diopsys even allows customers to buy NOVA, ARGOS, or RETINA PLUS *without* the VEP testing function:


Customize your chosen platform with one or all of our advanced visual electrophysiology modules (click on each to learn more):

Diopsys® ffERG (full field electroretinography)
Protocols for objectively evaluating cone and ganglion cell function.

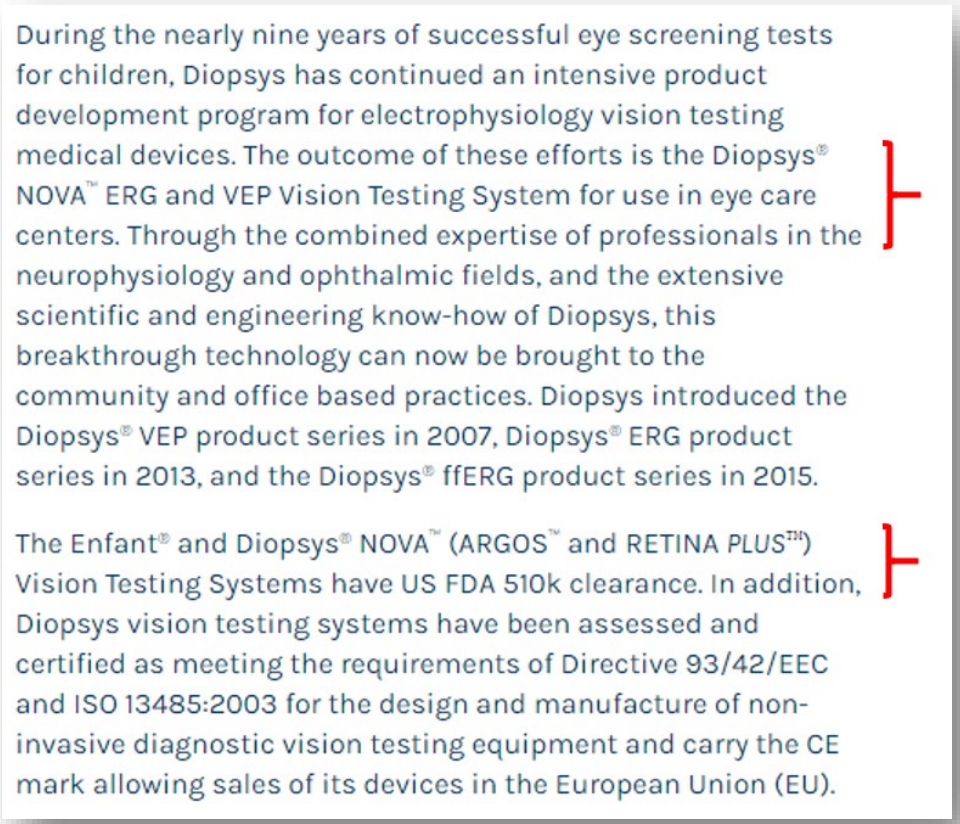
Diopsys® mfERG (multifocal electroretinography)
Protocols for objectively evaluating localized retinal function.

Diopsys® PERG (pattern electroretinography)
Protocols for objectively evaluating ganglion cell function.

Diopsys® VEP (visual evoked potential)
Protocols for objectively evaluating the function of the entire visual pathway.

Diopsys module selection

86. Diopsys proudly announces on its website that the Enfant and Diopsys NOVA (ARGOS and RETINA PLUS) Vision Testing Systems have 510k clearance but does so in misleading fashion:


During the nearly nine years of successful eye screening tests for children, Diopsys has continued an intensive product development program for electrophysiology vision testing medical devices. The outcome of these efforts is the Diopsys® NOVA™ ERG and VEP Vision Testing System for use in eye care centers. Through the combined expertise of professionals in the neurophysiology and ophthalmic fields, and the extensive scientific and engineering know-how of Diopsys, this breakthrough technology can now be brought to the community and office based practices. Diopsys introduced the Diopsys® VEP product series in 2007, Diopsys® ERG product series in 2013, and the Diopsys® ffERG product series in 2015.

The Enfant® and Diopsys® NOVA™ (ARGOS™ and RETINA *PLUS*™) Vision Testing Systems have US FDA 510k clearance. In addition, Diopsys vision testing systems have been assessed and certified as meeting the requirements of Directive 93/42/EEC and ISO 13485:2003 for the design and manufacture of non-invasive diagnostic vision testing equipment and carry the CE mark allowing sales of its devices in the European Union (EU).

87. Diopsys initially refers to the "Diopsys NOVA ERG and VEP Vision Testing System." However, the device that received clearance is the "Diopsys NOVA VEP Vision Testing System," without the "ERG." Conveniently, the full name is not used when Diopsys includes that NOVA, ARGOS, and RETINA PLUS are FDA cleared, implying that Diopsys received FDA clearance for its ERG testing.

88. Diopsys' failure to seek FDA approval for its ERG testing equipment was for good reason: Its ERG machine is based on faulty science and would likely not have been approved by the FDA. There are no peer-reviewed articles demonstrating Diopsys' equivalence to traditional ERG testing modalities.

89. A legitimate ERG test uses electrodes placed directly on the eye—via either a contact lens (BA electrodes), or a small wire (DTL electrodes). Some companies have experimented with ERG tests that utilize electrodes placed on the skin around the eye (eyelids). The amplitude of the signal produced by eyelid electrodes is lower and more difficult to interpret than that of a traditional ERG test performed with BA or DTL electrodes. In fact, the International Society for Clinical Electrophysiology of Vision (ISCEV) suggests that the added comfort provided to children by using eyelid electrodes may be offset by "greater electrode movement or smaller ERG amplitudes."[8] Because the signal must travel through skin, there is more "noise," diluting the already weak signal. However, as subtle abnormalities are typically less critical when examining younger patients, the weaker signal may be less problematic.[9]

90. For ERG testing, Diopsys exclusively uses an eyelid electrode, the Diopsys ERG Lid Sensor. The Lid Sensor has not been extensively studied and no peer reviewed publications evaluating it exist. Nor has it been evaluated or approved by the FDA.

91. On the Diopsys website, there is a "Clinical Support" tab that appears under the Vision Testing Systems. One of listed "research articles" claims that the Lid Sensor is compliant

[8] McCulloch, D.L., Marmor, M.F., Brigell, M.G. et al. ISCEV Standard for full-field clinical electroretinography (2015 update). Doc Ophthalmol 130, 1–12 (2015). https://doi.org/10.1007/s10633-014-9473-7

[9] *Id.*

with ISCEV ERG testing standards.[10] Anna Shengelia, the corresponding author, purports to review "critical areas of consideration when comparing electrodes for recording ERGs according to ISCEV Standards." When discussing Diopsys' methods, Shengelia strictly refers to "ERG testing," ignoring that 1) Diopsys performs three distinct ERG tests and 2) there are different ISCEV standards for each test.[11] Shengelia cites to the ISCEV 2015 ffERG Standard and treats it as if it applies to mfERG and PERG testing as well.

92. Shengelia writes that Diopsys' signal-averaging renders the lesser signal "inconsequential," and the narrow design and placement of the electrodes "minimizes the potential for noise contamination."[12] According to ISCEV's 2015 ffERG Standard, when using skin electrodes, signal averaging "may be required to obtain reliable responses" and "reduces variability and background noise and facilitates the estimation of variability."[13] Shengelia takes this to mean that just because Diopsys systems use signal averaging, the Lid Sensors are reliable and comport with ISCEV standards.

93. Because of the low signal strength and noise associated with skin sensors, ISCEV maintains that "[a]rtifact rejection must be a part of any averaging system."[14] Again, Shengelia takes this phrase and runs with it, suggesting that because Diopsys claims to use an algorithm for artifact rejection, the Lid Sensors are compliant with ISCEV and reliable. However, Shengelia ignores language from the 2015 ffERG Standard that warns against the use of skin electrodes on the lower eyelid as they "may not be suitable to evaluate attenuated pathological ERGs.[15]

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[10] A Shengelia, C Tello, J Siegfried, R Ritch. The Importance of Electrode Selection in ERG Testing

[11] Hoffmann, M.B., Bach, M., Kondo, M. et al. ISCEV standard for clinical multifocal electroretinography (mfERG) (2021 update); McCulloch, D.L., Marmor, M.F., Brigell, M.G. et al. ISCEV Standard for full-field clinical electroretinography (2015 update); Bach, M., Brigell, M.G., Hawlina, M. et al. ISCEV standard for clinical pattern electroretinography (PERG): 2012 update.

[12] A Shengelia, C Tello, J Siegfried, R Ritch. The Importance of Electrode Selection in ERG Testing

[13] McCulloch, D.L., Marmor, M.F., Brigell, M.G. et al. ISCEV Standard for full-field clinical electroretinography (2015 update)

[14] *Id.*

[15] *Id.*

94. Shengelia references a "recent study" that concludes "eye care providers can have confidence in Diopsys."[16] Like Shengelia's above-referenced claims, this assertion is largely baseless. The referenced study is her own, only tested the Diopsys system on 123 patients, and did not test the Diopsys system against another system.[17] Most crucially, this research article was never published nor was it peer-reviewed; it is nothing more than an unsubstantiated, internal document that has never been independently validated or had its findings confirmed.

95. In another of Shengelia's studies, she did measure the Lid Sensor against one BA and one DTL electrode and found that Diopsys' sensor produced the lowest standard deviation and best test repeatability of the three.[18] However, Shengelia fails to note that the Diopsys' sensor had the weakest mean amplitude, less than half the strength of the DTL electrode.[19] Each of Shengelia's studies and articles bear the hallmarks of illegitimate research pieces as they do not include dates of publication or references. Additionally, Shengelia, is a fellow in Pulmonary/Critical Care with no expertise in eye care.

96. On its website, Diopsys refers to its ERG Lid Sensors as "clinically tested," but the only citation is to Shengelia's study.[20]

97. Moreover, Diopsys' ERG process does not meet basic industry standards. For example, ISCEV specifies six standard ERGs that should be recorded during an ffERG test.[21] Before the four dark-adapted ERGs are recorded, the patient should be dark-adapted for at least twenty minutes.[22] Before the two light-adapted ERGs are recorded, the patient should be light-adapted for at least ten minutes.[23] Despite ISCEV standards calling for at least thirty minutes of

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[16] A Shengelia, C Tello, J Siegfried, R Ritch. The Importance of Electrode Selection in ERG Testing
[17] A. Shengelia, P. Derr, A. Gonzalez-Garcia, M. Ghassibi, J. Chien, M. C. Tello, R. Ritch. Steady-State Pattern Electroretinogram (ssPERG) Fixed Protocol Reference Ranges of Healthy Eyes
[18] A. Shengelia, P. Derr, C. Tello. Evaluation of Pattern ERG responses using various electrodes
[19] *Id.*
[20] https://diopsys.com/visual-electrophysiology-products/erg-sensors/
[21] McCulloch, D.L., Marmor, M.F., Brigell, M.G. et al. ISCEV Standard for full-field clinical electroretinography (2015 update)
[22] *Id.*
[23] *Id.*

patient adaption, Diopsys markets its products as able to perform ERG tests in minutes, saving physicians time and money.

98. Diopsys also claims that its ffERG testing can be performed without dilating the patient's pupils. This is directly in conflict with ISCEV standards which maintain pupils should be maximally dilated before performing an ffERG test (2015 ffERG Standard).[24]

99. Similarly, mfERG testing requires use of a contact electrode; an eyelid or skin electrode is unacceptable, per ISCEV guidelines. Nonetheless, Diopsys claim that its eyelid electrode allows for performance of mfERG testing.

V. CAUSES OF ACTION

FIRST CAUSE OF ACTION

On Behalf of the United States against All Defendants

Federal False Claims Act, Presenting False Claims

31 U.S.C. § 3729(a)(1)(A)

100. Relator incorporates herein by reference and realleges allegations contained in paragraphs 1 through 100 above as though fully set forth herein

101. Defendants knowingly (as defined in 31 U.S.C. § 3729(b)(1)) presented or caused to be presented false claims for payment or approval to an officer or employee of the United States, including through the Medicare program, state Medicaid programs (which are partially funded by the United States), and other federally administered health care programs that include, but are not limited to, TRICARE, CHAMPVA, and the Federal Employee Health Benefit Program.

102. The conduct of Defendants violated 31 U.S.C. § 3729(a)(1)(A) and was a substantial factor in causing the United States to sustain damages in an amount according to proof.

[24] McCulloch, D.L., Marmor, M.F., Brigell, M.G. et al. ISCEV Standard for full-field clinical electroretinography (2015 update)

SECOND CAUSE OF ACTION

On Behalf of the United States against All Defendants

Federal False Claims Act, Making or Using False Records or Statements Material to Payment or Approval of False Claims

31 U.S.C. § 3729(a)(1)(B)

103. Relator incorporates herein by reference and realleges the allegations contained in paragraphs 1 through 100 above as though fully set forth herein.

104. Defendants knowingly (as defined in 31 U.S.C. § 3729(b)(1)) made, used, or caused to be made or used false records or statements material to false or fraudulent claims.

105. Defendants knowingly made, used, and/or caused to be made and used false records and statements, including but not limited to claims, bills, invoices, requests for reimbursement, and records of services, that were material to the payment or approval of charges by the United States, including through the Medicare program, state Medicaid programs (which are partially funded by the United States), and other federally-administered health care programs that include, but are not limited to, TRICARE, CHAMPVA, and the Federal Employee Health Benefit Program.

106. The conduct of Defendants violated 31 U.S.C. § 3729(a)(1)(B) and was a substantial factor in causing the United States to sustain damages in an amount according to proof.

THIRD CAUSE OF ACTION

On Behalf of the United States against All Defendants

Conspiracy to Violate the False Claims Act

31 U.S.C. § 3729(a)(1)(C)

107. Relator incorporates herein by reference and realleges the above allegations.

108. Defendants, between and amongst themselves, and others, conspired to defraud the United States, including through the Medicare program, state Medicaid programs (which are partially funded by the United States), and other federally-administered health care programs that include, but are not limited to, TRICARE, CHAMPVA, and the Federal Employee Health Benefit Program, and did so by: (1) presenting or causing to be presented false claims for payment or

approval to an officer or employee of the United States, (2) making, using, or causing to be made or used false records or statements material to false or fraudulent claims.

109. As a result of Defendants' actions, the United States has been and will continue to be, severely damaged.

FOURTH CAUSE OF ACTION

On Behalf of the State of California against Defendants Diopsys, Inc., Sean Bahri, M.D. Sean S. Bahri, M.D., Inc., Clark Tsai, M.D. and Clark S Tsai, M.D., Inc.

Violation of the Insurance Fraud Prevention Act

(Cal. Ins. Code § 1871.7(b))

110. Relator incorporates herein by reference and realleges allegations contained in paragraphs 1 through 100 above as though fully set forth herein.

111. By virtue of the conduct alleged herein, Defendants, and each of them intentionally and repeatedly violated California Insurance Code § 1871.7(b) in that Defendants, and each of them, knowingly violated California Penal Code § 550 by engaging in the following conduct:

a. Knowingly presenting or causing to be presented false or fraudulent claims for the payment of a loss or injury under a contract of insurance; and/or

b. Knowingly preparing, making or subscribing writings, with the intent to present or use them, or allow them to be presented, in support of a false or fraudulent claim; and/or

c. Presenting or causing to be presented written or oral statements as part of, or in support of claims for payment or other benefit pursuant to an insurance policy, knowing that the statement contains false or misleading information concerning material facts; and/or

d. Preparing or making any written or oral statements that were intended to be presented to an insurer in connection with, or in support of, claims or benefits pursuant to an insurance policy, knowing that the statement contain false or misleading information concerning material facts; and/or

e. Aiding, abetting, soliciting, assisting, or conspiring with any person to engage in (a) through (d) above.

112. As a result of such conduct on the part of Defendants, the State of California has been damaged in substantial amounts and is entitled to damages and penalties in accordance with California Insurance Code § 1871.7, to be determined at trial.

FIFTH CAUSE OF ACTION

On behalf of the State of California Against Defendants Diopsys, Inc., Sean Bahri, M.D., Sean S. Bahri, M.D., Inc., Clark Tsai, M.D. and Clark S Tsai, M.D., Inc.

California False Claims Act

Cal. Gov't Code §§ 12651(a)(1)–(3), (8)

113. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 100 above as though fully set forth herein.

114. This is a claim for treble damages and penalties under the California False Claims Act, Cal. Gov't Code §§ 12651(a)(1)-(3), (8).

115. Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of California for payment or approval.

116. Defendants knowingly made, used, or caused to be made or used false records or statements, and omitted material facts, to induce the State of California to approve and pay such false and fraudulent claims.

117. Defendants knowingly conspired to commit a violation of section 12651.

118. In the alternative, Defendants were the beneficiary of an inadvertent submission of a false claim, subsequently discovered the falsity of the claim, and failed to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

119. The State of California, unaware of the falsity of the records, statements, and claims that Defendants made or caused to be made, paid claims that would not be paid but for Defendants' illegal conduct.

120. Defendants have damaged the State of California in a substantial amount to be

determined at trial.

121. Additionally, the State of California is entitled to the maximum penalty for each and every violation alleged herein.

SIXTH CAUSE OF ACTION

On behalf of the State of Florida Against Defendants Diopsys, Inc., James Powers, M.D., and Healthy Vision Property, LLC

Florida False Claims Act

Fla. Stat. Ann. §§ 68.082(2)(a)-(b)

122. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 100 above as though fully set forth herein.

123. This is a claim for treble damages and penalties under the Florida False Claims Act, Fla. Stat. Ann. §§ 68.081 through 68.092.

124. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims for payment or approval.

125. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements, material to false and fraudulent claims.

126. The State of Florida, unaware of the falsity of the records, statements, and claims made, used, presented, or caused to be made, used, or presented by Defendants, paid claims that would not be paid but for Defendants' unlawful conduct.

127. By reason of Defendants' acts, the State of Florida has been damaged in a substantial amount to be determined at trial.

128. Additionally, the State of Florida is entitled to the maximum penalty for each and every violation alleged herein.

SEVENTH CAUSE OF ACTION

On behalf of the State of Hawaii Against Defendants Diopsys, Inc.,

Haidong Yang and Hawaii Retina

Hawaii False Claims Act

Haw. Rev. Stat. §§ 661-21(a)(1)–(2)

129. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 100 above as though fully set forth herein.

130. This is a claim for treble damages and penalties under the Hawaii False Claims Act.

131. Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Hawaii for payment or approval.

132. Defendants knowingly made, used, or caused to be made or used false records or statements, and omitted material facts, to induce the State of Hawaii to approve and pay such false and fraudulent claims.

133. The State of Hawaii, unaware of the falsity of the records, statements, and claims that Defendants made or caused to be made, paid claims that would not be paid but for Defendants' illegal conduct.

134. Defendants have damaged the State of Hawaii in a substantial amount to be determined at trial.

135. Additionally, the State of Hawaii is entitled to the maximum penalty for each and every violation alleged herein.

EIGHTH CAUSE OF ACTION

On behalf of the State of Maryland Against Defendants Diopsys, Inc.,

David Warrow, M.D., Allen Hu, M.D., John Wroblewski, M.D.

and Cumberland Valley Retina Consultant, P.

Maryland False Claims Act

Md. Code Ann., Health-Gen. §§ 2-602(a)(1)–(2)

136. Relator realleges and incorporates by reference the allegations contained in

paragraphs 1 through 100 above as though fully set forth herein.

137. This is a claim for treble damages and penalties under the Maryland False Health Claims Act.

138. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Maryland for payment or approval.

139. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records or statements, and omitted material facts, to induce the State of Maryland to approve and pay such false and fraudulent claims.

140. The State of Maryland, unaware of the falsity of the records, statements, and claims that Defendants made or caused to be made, paid claims that would not be paid but for Defendants' illegal conduct.

141. Defendants have damaged the State of Maryland in a substantial amount to be determined at trial.

142. Additionally, the State of Maryland is entitled to the maximum penalty for each and every violation alleged herein.

NINTH CAUSE OF ACTION

On behalf of the State of New Jersey against Defendants Diopsys, Inc., Vatsal Doshi, M.D. and Cumberland Valley Specialists of New Jersey, LLC

New Jersey False Claims Act

N.J. Stat. §§ 2A:32C-3(a)–(b)

143. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 100 above as though fully set forth herein.

144. This is a claim for treble damages and penalties under the New Jersey False Claims Act.

145. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of New Jersey for payment or approval.

146. By virtue of the acts described above, Defendants knowingly made, used, or caused

to be made or used false records or statements, and omitted material facts, to induce the State of New Jersey State to approve and pay such false and fraudulent claims.

147. The State of New Jersey, unaware of the falsity of the records, statements, and claims that Defendants made or caused to be made, paid claims that would not be paid but for Defendants' illegal conduct.

148. Defendants have damaged the State of New Jersey in a substantial amount to be determined at trial.

149. Additionally, the State of New Jersey is entitled to the maximum penalty for each and every violation alleged herein.

TENTH CAUSE OF ACTION

On behalf of the State of New York against Defendants Diopsys, Inc.,

Ilona Genis, M.D., and Ilonia Genis MD, P.C.

New York False Claims Act

N.Y. State Fin. §§ 189(1)(a)–(b)

150. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 100 above as though fully set forth herein.

151. This is a claim for treble damages and penalties under the New York False Claims Act.

152. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records or statements, and omitted material facts, to induce the State of New York to approve and pay such false and fraudulent claims.

153. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of New York for payment or approval.

154. The State of New York, unaware of the falsity of the records, statements, and claims that Defendants made or caused to be made, paid claims that would not be paid but for Defendants illegal conduct. The fact that the State of New York may have paid for false or fraudulent claims subsequent to the filing of this action does not negate the materiality of the Defendants'

wrongdoing and noncompliance. Even though many, if not most, of the prescriptions for medications were tainted by improper financial inducements and prior authorization fraud, some are legitimate, and the State of New York has no practical means of discerning, on a prepayment basis, which prescriptions were tainted by kickbacks or prior authorization fraud and which are not. In addition, because many of the medications Defendants dispense are life-saving drugs, a blanket suspension of payments to the Defendants could cause substantial harm—and even fatalities.

155. Defendants have damaged the State of New York in a substantial amount to be determined at trial.

156. Additionally, the State of New York is entitled to the maximum penalty for each and every violation alleged herein.

ELEVENTH CAUSE OF ACTION

On behalf of the State of Oklahoma against Defendant Diopsys, Inc. and Gregory Clay

Oklahoma Medicaid False Claims Act

Okla. Stat. tit. 63 §§ 5053.1(B)(1)–(2)

157. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 100 above as though fully set forth herein.

158. This is a claim for treble damages and penalties under the Oklahoma Medicaid False Claims Act.

159. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Oklahoma for payment or approval.

160. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records or statements, and omitted material facts, to induce the State of Oklahoma to approve and pay such false and fraudulent claims.

161. The State of Oklahoma, unaware of the falsity of the records, statements, and claims that Defendants made or caused to be made, paid claims that would not be paid but for Defendants' illegal conduct.

162. Defendants have damaged the State of Oklahoma in a substantial amount to be determined at trial.

163. Additionally, the State of Oklahoma is entitled to the maximum penalty for each and every violation alleged herein.

TWELFTH CAUSE OF ACTION

On behalf of the State of North Carolina against Defendants Diopsys, Inc., Charles Zwerling, M.D. and Goldsboro Eye Clinic, PLLC

North Carolina False Claims Act

N.C. Gen. Stat. §§ 1-607(a)(1)–(2)

164. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 100 above as though fully set forth herein.

165. This is a claim for treble damages and penalties under the North Carolina False Claims Act.

166. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of North Carolina for payment or approval.

167. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records or statements, and omitted material facts, to induce the State of North Carolina to approve and pay such false and fraudulent claims.

168. The State of North Carolina, unaware of the falsity of the records, statements, and claims that Defendants made or caused to be made, paid claims that would not be paid but for Defendants' illegal conduct.

169. Defendants have damaged the State of North Carolina in a substantial amount to be determined at trial.

170. Additionally, the State of North Carolina is entitled to the maximum penalty for each and every violation alleged herein.

THIRTEENTH CAUSE OF ACTION

On Behalf of the State of Texas against Defendants Diopsys, Inc., David Mora, David Saul Mora, O.D., Ph.D., P.C., Terry Foster, Randal Cox

Texas Medicaid Fraud Prevention Act

Tex. Hum. Res. Code Ann. §§ 36.002(1), (2), (4), and (5)

171. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 100 above as though fully set forth herein.

172. This is a claim for treble damages and penalties under the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.001, et seq.

173. By virtue of the acts described above, Defendants have knowingly made or caused to be made false statements or misrepresentations of material facts to permit it to receive payments from the Texas Medicaid program that were not authorized or that were greater than the payments that were authorized.

174. By virtue of the acts described above, Defendants have knowingly concealed or failed to disclose information, thus permitting them to receive payments from the Texas Medicaid program that were not authorized or that were greater than the payments that were authorized.

175. By virtue of the acts described above, Defendants have knowingly made or caused to be made false statements or misrepresentations of material facts regarding information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program.

176. By virtue of the acts described above, Defendants have knowingly paid, charged, solicited, accepted, or received, in addition to amounts paid under the Medicaid program, gifts, money, donations, or other consideration as a condition to the provision of a service or product or the continued provision of a service or product, the cost of which is paid for, in whole or in part, under the Medicaid program.

177. The State of Texas, unaware of the falsity of all such claims and statements material to payments made, has paid such false or fraudulent claims that would not be paid but for

Defendants' illegal conduct.

178. By reason of Defendants' acts, the State of Texas has been damaged in a substantial amount to be determined at trial.

179. The Texas Medicaid Fraud Prevention Act is a statute of absolute liability. There are no statutory, equitable, or common law defenses for any violation of its provisions. Furthermore, Texas case law provides that the defenses of estoppel, laches, and limitations are not available against the State of Texas as a sovereign. *State v. Durham*, 860 S.W.2d 63, 67 (Tex. 1993).

180. Under the Texas Medicaid Fraud Prevention Act, each Defendant is liable to the State of Texas for the amount of any payments or the value of any monetary or in-kind benefits provided under the Medicaid program, directly or indirectly, as a result of its unlawful acts; two times the amount of those payments or the value of the benefit; pre-judgment interest on the amount of those payments or the value of the benefit; and a civil penalty for each unlawful act committed, in addition to the fees, expenses, and costs of the Attorney General and the Relator in investigating and obtaining civil remedies in this case. Tex. Hum. Res. Code §§ 36.052, 36.007, 36.110(c).

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, by and through the Relator, prays judgment in its favor and against Defendants as follows:

1. That judgment be entered in favor of Plaintiff United States Of America *ex rel.* Atul Jain, M.D., according to proof on the first, second, and third causes of action for damages as provided by 31 U.S.C. § 3729(a)(1), in the amount of:

i. Triple the amount of damages sustained by the United States;

ii. Civil penalties between $11,181 and $22,363 for each false claim;

iii. Recovery of costs, attorney's fees, and expenses;

iv. Pre- and post-judgment interest;

v. Such other and further relief as the Court deems just and proper.

2. Further, as to all causes of action, Relator on his own behalf, requests that he receives such maximum amount as permitted by law, of the proceeds of this action or settlement of this action collected by the United States, California, Florida, Hawaii, Maryland, New Jersey, New York, North Carolina, Oklahoma, and Texas, plus an amount for his reasonable expenses incurred, plus reasonable attorney's fees and costs of this action. Relator requests that his percentage be based upon the total value recovered, including any amounts received from individuals or entities not parties to this action. Relator also requests that he be awarded all costs of this action, including attorney's fees and expenses;

3. That this Court enter judgment against Defendants for damages and penalties under California False Claims Act, Cal. Gov't Code §§ 12651(a)(1)–(2); California Insurance Frauds Prevention Act, Cal. Ins. Code § 1871.7(b); Florida False Claims Act, Fla. Stat. Ann. §§ 68.082(2)(a)-(b); Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-21(a)(1)-(2); Maryland False Claims Act, Md. Code Ann., Health-Gen. §§ 2-602(a)(1)-(2); New Jersey False Claims Act, N.J. Stat. §§ 2A:32C-3(a)–(b); New York False Claims Act, N.Y. State Fin. §§ 189(1)(a)–(b); North Carolina Medicaid False Claims Statute, N.C. Gen. Stat. §§ 1-607(a)(1)–(2); Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63 §§ 5053.1(B)(1)–(2); Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. §§ 36.002(1), (2), (4), and (5).

4. That Relator recover such other and further relief as the Court deems just and

proper.

Dated: October 6, 2021

Respectfully Submitted,

/s/ David C. Williams

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